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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,134	03/26/2004	Anant V. Hegde	PAVA-003/01US	8838
23419	7590	10/03/2005	EXAMINER	
COOLEY GODWARD, LLP			REIDEL, JESSICA L	
3000 EL CAMINO REAL			ART UNIT	
5 PALO ALTO SQUARE			PAPER NUMBER	
PALO ALTO, CA 94306			3762	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/810,134	Applicant(s) HEGDE ET AL.	
	Examiner Jessica L. Reidel	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>05/04/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are informal. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-10 and 12-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Scorvo (U.S. 2004/0010180). As to Claims 1-5, 12-15, 19-20 and 22-23, Scorvo discloses a cardiac apparatus 300 comprising a cardiac assist device or jacket, read as a covering 20, including a first portion and a second portion configured to at least partially encircle the heart with the first and second portions adjacent to each other (see Scorvo Abstract, Fig. 9 and page 4, paragraphs 50-51). The Examiner takes the position that the first portion of the covering 20 is

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represented as the portion of the covering 20 to the left of lateral edge 48, extending clockwise backwards, and ending at the back of the covering 20 where the left pulmonary vein extends upwards (see Scorvo Figs. 2A and 3A-3B). The Examiner also takes the position that the second portion of the covering is represented as the portion of the covering 20 to the right of lateral edge 46, extending counterclockwise backwards, and ending at the back of the covering 20 where the left pulmonary vein extends upwards (see Scorvo Figs. 2A and 3A-3B).

Scorvo discloses that the apparatus 300 also comprises a size adjustment mechanism including contractile transducers (that comprise dielectric electrostrictive electroactive polymer actuators) 102 and 104, including a first end and a second end, coupled to the mesh fabric 100, read as a coupling member of the covering 20. The Examiner takes the position that the first end of the electroactive polymer actuators are represented as woven into the portion of the covering 20 to the left of lateral edge 48, extending clockwise backwards, and ending at the back of the covering 20 where the left pulmonary vein extends upwards (see Scorvo Figs. 2A and 3A-3B). The Examiner takes the position that the second end of the electroactive polymer actuators are represented as woven into the portion of the covering 20 to the right of lateral edge 46, extending counterclockwise backwards, and ending at the back of the covering 20 where the left pulmonary vein extends upwards (see Scorvo Figs. 2A and 3A-3B). Scorvo further discloses that as the actuators 102 and 104 are shortened, the volume 26 of the covering 20 is compressed. It is inherent that during this compression, the second portion of the covering 20 moves towards the first portion of the covering 20 via the second end of the electroactive polymer extending away from the first end of the electroactive polymer (see Scorvo Fig. 6 and pages 4-5, paragraphs 54-

56). Scorvo also discloses an alternative embodiment of the contractile transducers (that comprise multi-layered electroactive polymer actuators) 120 of a cardiac assist device 122.

4. As to Claims 6, 16 and 24, Scorvo discloses that the cardiac apparatus 300 comprises releasable latches 50 and 52 for selectively adjusting the volumetric size of the covering 20 by retaining the first portion of the covering at desired spacing with respect to the second portion of the covering (see Scorvo Fig. 3B and page 3, paragraph 46).

5. As to Claims 7-10, 17-18 and 25-26, Scorvo further discloses, that the cardiac apparatus 300 comprises a sensor 114 to detect a cardiac cycle of the heart and a controller 308 coupled to the sensor and to the contractile transducers (that comprise electroactive polymer actuators) 102, 104. The controller 308 generates signals to drivers 304, 306 to selectively actuate the actuators 102, 104 according to a treatment regimen or in response to a cardiac parameter or characteristic sensed by sensor 114 (see Scorvo page 5, paragraph 59 and page 6, paragraph 66-68). As previously mentioned, Scorvo also discloses an alternative embodiment of the contractile transducers (that comprise multi-layered electroactive polymer actuators) 120 of a cardiac assist device 122. Referring to Scorvo Fig. 7, the Examiner takes the position that the top actuator 120 is a first electroactive polymer actuator and the bottom actuator 120 is a second electroactive polymer actuator. The Examiner also takes the position that in this embodiment, both first and second electroactive polymer actuators 120 include a first end and a second end, where the first end of the electroactive polymer actuators are coupled to the first portion of the covering, and the second end of the electroactive polymer actuators are coupled to the second portion of the covering, where the second end of the electroactive polymer actuator is oriented such that, upon actuation of the actuators 120, the second end of the actuators both extend away from the first

end of the actuators actuator to move the second portion of the covering towards the first portion of the covering (see Scorvo Figs. 6-7 and pages 4-5, paragraphs 54-56).

6. As to Claim 21, Scorvo also discloses that the covering 20 includes a mesh material, read as a frame 40, that includes a first support member and a second support member. In reference to Scorvo Fig. 6, the Examiner takes the position that the first support member is the mesh extending from the bottom left and up to the top right (axes XB) and the second support member is the mesh extending down from the top left to the bottom right (axes XA) and that both support members are spaced apart from each other by the rectangular diamond spaces 112 between each member. Scorvo also discloses contractile transducers (that comprise dielectric electrostrictive electroactive polymer actuators) 120. Referring to Scorvo Fig. 7, the Examiner takes the position that the actuators 120 are formed as a film extending between the first support member of the covering 20 and the second support member and are configured to expand in any direction, including inwardly upon actuation to compress the heart (see Scorvo page 5, paragraph 56).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scorvo in view of Couvillon, JR. (U.S. 2004/0167375). Scorvo discloses the claimed invention as discussed above except that the controller does not actuate the first electroactive polymer actuator at a first

actuation level and the second electroactive polymer actuator at a second actuation level that is different from the first actuation level.

Couvillon JR., however, discloses a cardiac assist device 100 for assisting with the function of a heart that includes a compressor, read as a covering 102 positioned adjacent the epicardial wall of the heart. One or more electroactive polymer actuators 110 drive the covering 120 and the subsequent pressure exerted against the heart improves overall heart function (see Couvillon JR. Abstract, Fig. 2 and page 2, paragraph 22). Couvillon JR. discloses that the device 100 also comprises computing device 106 that is capable of providing signals which cause the actuators 110 closer to the apex of heart to contract first and those further from the apex to contract later. The Examiner takes the position that a first actuator, located closer to the apex of the heart, is actuated at a first actuation level and a second actuator, located further from the apex, is actuated at a second actuation level, different from the first actuation level where different is synonymous with the actuation level occurring at a different time. Couvillon JR. also discloses that this type of pulsation technique provides a cardiac assist device that more closely mimics the natural "wringing", propagating-pulsing action of heart (see Couvillon JR. page 3, paragraph 32). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the actuation of Scorvo in view of Couvillon JR. to actuate the first electroactive polymer actuator at a first actuation level and the second electroactive polymer actuator at a second actuation level that is different from the first actuation level in order to mimic the natural "wringing", propagating-pulsing action of heart and better the invention.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

1. Alferness et al. (U.S. 6,169,922) discloses a device for treating cardiac disease of a heart that includes a jacket, read as a covering, of flexible material defining a volume between an open upper end and a lower end, a first and a second grid of electrodes where the grids are disposed to be in overlying relation to individual ones of the opposite sides of the heart when the covering is secured to the heart.

2. Alferness (U.S. 6,126,590) discloses a cardiac reinforcement device (CRD) and method for the treatment of cardiomyopathy where the device comprises a covering the further comprises a first and second portion and releasable latch members.

3. Shahinpoor (U.S. 6,464,655) discloses a cardiac assist device comprising a plurality of soft fingers that work in harmony by means of a micro-processor, or other actuators such as electroactive polymer actuators, to assist the pumping of the heart.


4. Pelrine et al. (U.S. 6,809,462) discloses in column 30, lines 33-49, that sensors of the present invention are also well suited for prosthetic and medical applications where a biological parameter or parameter related to medical instrumentation is to be sensed. The biological parameter may include the strain displacement, or other time varying parameter, of a tissue such as bone, muscle, or skin. For example, a sensor may be mechanically and/or electrically coupled to a portion of a person's head for detecting muscle strain, heart rate, pressure, etc.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The examiner can normally be reached on Mon-Thurs 7-4:30 and every other Friday 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3762

Jessica L. Reidel 